UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,151	06/08/2005	Giovanni Mogna	38315	3249

116 7590 06/26/2008

PEARNE & GORDON LLP
1801 EAST 9TH STREET
SUITE 1200
CLEVELAND, OH 44114-3108

EXAMINER	
BADR, HAMID R	

ART UNIT	PAPER NUMBER
1794	

MAIL DATE	DELIVERY MODE
06/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,151	MOGNA, GIOVANNI	
	Examiner	Art Unit	
	HAMID R. BADR	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/08/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Objection to Specification

The specification is objected to for not including a "Brief Description of the Drawings" section.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the microorganism(s) is/are essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism(s) is/are not so obtainable or available, the requirements of 35 USC 112 may be satisfied by deposit(s) of the microorganism(s). The specification does not disclose a repeatable process to obtain the microorganism(s) and it is not clear from the specification or record that the microorganism(s) is/are readily available to the public.

This rejection may be overcome by establishing that the each microorganism identified is readily available to the public and will continue to be so for a period of 30

years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein.

If the depository is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his/her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney over his/her registration number, showing that,

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon the granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and,

(d) the deposit will be replaced if it should ever become inviable.

The specification must also state the date of deposit(s), the number(s) granted the deposit(s) by the depository and the name and address of the depository.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 16-24 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 16-24 and 27 are indefinite for the phrase “to improve coagulation”. It is unclear what is meant by “to improve coagulation”. It is unclear what the applicant regards as the invention.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 16-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 5,942,263; hereinafter R1) in view of Sandine et al. (US 4,205,132; hereinafter R2) and Yamauchi et al. (US 5,527,505; hereinafter R3).

7. R1 discloses a method for manufacturing cheese including pre-acidifying milk, ripening milk to yield cheese milk, coagulating the milk by adding a coagulant to yield a coagulum, cutting the coagulum, separating the curd from whey, salting , milling and molding the curds (Abstract).

8. R1 teaches adding the starter to the milk and incubating at 34C to reduce the pH to 6.25. (Col. 3, lines 57-59)

9. R1 teaches using Lactobacillus lactis. It also teaches using a blend of different starter cultures. Starter culture is typically added at 72 ml starter per 1000 lbs. of milk or 0.75% (wt/wt) (Col. 4, lines 7-14). Furthermore, the rate of culture addition at 0.01-1.0% of milk is normal in the art. R1 also discloses that a mixture of mesophilic and thermophilic starter cultures may be used (Col. 4, lines 9-11). Those skilled in the art know that the starter culture is added before coagulating the milk, and as such the improvement in milk coagulation will be inherent in cheese making processes where a starter culture is employed.

10. R1 teaches using a coagulant such as chymosin to produce cheese curd. Further details of the process are given by R1.

11. R1 is silent regarding the use of anhydrous form of starters, the number of bacteria added to the milk, or addition of starters to the raw (unpasteurized) milk.

12. R2 discloses the production of lyophilized starter cultures which are storage stable (Abstract).

13. R2 gives a number of lactic acid producing bacteria which may be included in the lyophilized preparation. (Col. 3, lines 29-39).

14. R2 teaches that the bacteria which are best adapted to the process of the invention are those which are used to produce lactic acid in milk for cheese making (Col. 4, lines 43-45).

15. R2 teaches that a liquid culture contains at least about 10^8 to 10^{15} cells per ml. Given that about 15 ml starter culture is used for 220 pounds (100 liters) of milk (paragraph 9 above) and assuming a starter containing 10^{10} cells per ml, the total number of cells added to the milk will be about 1.5×10^{11} cells per 100 liters.

16. R1 and R2 are silent regarding the addition of starter cultures to raw (unpasteurized) milk.

17. R3 discloses a fermented milk with a controlled acidity increase during storage and transportation. The fermented milk can be manufactured by inoculating raw milk with *Lactococcus lactis subsp. Lactis* together with other lactic acid bacteria to be used for fermenting the raw milk (Abstract).

18. It would have been obvious to one of ordinary skill in the art at the time the invention was made, to modify the teachings of R1 and implement the teachings of R2 by using anhydrous (lyophilized) cultures and adopt the teachings of R3 to add the starter cultures to raw (unpasteurized) milk. One would do so to benefit from acidification of milk before coagulating the milk to make cheese which would affect the texture and/or organoleptic characteristics of the final product, and the acidified raw milk will also storage and transportation advantages. Absent any evidence to contrary and based on the combined teachings of the cited references there would be a reasonable expectation of success in acidifying the milk and coagulating it to make cheese.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. CH 635985 is a Chinese reference; EP0312359 is concerned with organic acid coagulation of milk and only gives a general description of starter cultures and rods and cocci. WO 99/33351 is a French reference using starter cultures with pasteurize milk and citric acid as the coagulant. EP 0505164 uses a mixture of Streptococci and Lactobacilli with specific reference to Lactobacillus lactis ATCC 11454 and is concerned with the preservation of milk and not the coagulation of it.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-T 5:00 to 3:30 (Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R Badr
Examiner
Art Unit 1794

/Callie E. Shosho/
Supervisory Patent Examiner, Art Unit 1794